DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
12709 Twinbrook Parkway
Rockville, Maryland 20850

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Josephine M. Torrente
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street N.W.
Suite 1200
Washington D.C. 20005-5929

Re: 2004P-0334

Dear Ms. Torrente:

This is in response to your petition, dated July 23, 2004. In your petition, you request that the Commissioner of Food and Drugs take action to require manufacturers of reprocessed single-use electrosurgical cutting and coagulation devices and accessories to submit validation data, including cleaning, sterilization, and functional performance data, demonstrating that each device will remain substantially equivalent to its predicate device after the maximum number of times the device is intended to be reprocessed.

On September 29, 2005, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) published a notice entitled "Medical Devices; Reprocessed Single-Use Devices; Termination of Exemption from Premarket Notification; Requirement for Submission of Validation Data (enclosed)." The notice addresses the concerns you have identified in your petition. The FDA has added laparoscopic and endoscopic electrosurgical accessories to the list of reprocessed single-use devices (SUDs) currently subject to premarket notification requirements that will now require submission of supplemental validation data regarding cleaning, sterilization, and functional performance. In addition, the agency has also added noncompression heart stablilizers to the list of critical reprocessed SUDs whose exemption from premarket notification requirements has been terminated and for which validation data are now necessary in a premarket notification.

If you have any questions about this response, please contact Myrna Hanna of our Regulations Staff at (301) 827-2971.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health

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